UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

EDWARD BAKER and JACK MILLER, on behalf of themselves and all others similarly situated, Plaintiffs, v. LIVANOVA PLC, SORIN GROUP DEUTSCHLAND GMBH, and SORIN GROUP USA, INC. Defendants.	CIVIL ACTION CLASS ACTION NO.: 1:16-cv-00260-JEJ **JURY TRIAL DEMANDED**

FIRST AMENDED CLASS ACTION COMPLAINT

Plaintiffs, Edward Baker and Jack Miller, individually and on behalf of all similarly situated persons, by and through their undersigned attorneys, allege the following upon information and belief, except for those allegations pertaining to Plaintiffs, which are based on personal knowledge.

NATURE OF THE ACTION

1. Plaintiffs, Edward Baker and Jack Miller (hereinafter "Plaintiffs"), bring this action individually, and on behalf of all persons similarly situated in the Commonwealth of Pennsylvania, who were unknowingly exposed to a potentially fatal bacteria during open heart surgery.

2. Plaintiffs and the Class were exposed to nontuberculous mycobacterium ("NTM") through a Sorin 3T Heater-Cooler System used to regulate their blood temperature during open heart surgeries at two hospitals, WellSpan York Hospital ("WellSpan") and Penn State Milton S. Hershey Medical Center ("Hershey Medical Center" or "Hershey").

3. As further described below, Defendants, LivaNova PLC, Sorin Group Deutschland Gmbh, and Sorin Group USA Inc. knew or should have known that design and/or manufacturing defects in their Sorin 3T Heater-Cooler System causes bacterial colonization to which patients are exposed during surgery, thus posing a significant risk of bodily injury or death.

4. Through this action, Plaintiffs and the Class seek medical monitoring to screen for NTM infection, and pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq*., seek a declaration that the Sorin 3T Heater-Cooler System was and is defective and unsafe for its intended use.

JURISIDCTION AND VENUE

5. This Court has subject matter jurisdiction over this action pursuant to the diverse citizenship of the parties. 28 USCS § 1332(a)(2). Plaintiffs are citizens and residents of the Commonwealth of Pennsylvania. Defendant, LivaNova PLC, is a foreign corporation incorporated under the laws of England and Wales with a corporate headquarters in Milan, Italy. Defendant, Sorin Group Deutschland Gmbh, is a foreign corporation headquartered in Munich, Germany. Defendant, Sorin Group USA Inc. is the U.S. distributor of the medical device at issue, with a principal place of business in Arvada, Colorado.

6. Personal jurisdiction exists over Defendants, LivaNova PLC and Sorin Group Deutschland Gmbh, in the U.S. due to the general and specific contacts they maintain in the U.S. Defendants maintain those contacts presently and did so at all times material to this action. The amount in controversy exceeds $75,000.

7. This Court additionally has subject matter over this action pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d). There are more than 3600 putative class members, who are or were citizens of the Commonwealth of Pennsylvania at the time of their exposure, and the Defendants are each citizens of another state and/or a foreign country. The aggregate of the Class Members' claims is more than $5 million dollars, exclusive of interests and costs.

8. Venue is proper in this District pursuant to 28 U.S.C. § 1391 as a substantial part of the events and/or omissions giving rise to the Plaintiffs' claims emanated from activities within this jurisdiction and Defendants conduct substantial business within this jurisdiction.

THE PARTIES

9. Plaintiff and proposed Class Representative Edward Baker is an adult individual, a resident and citizen of Pennsylvania residing in Dallastown, PA. On March 18, 2015, Mr. Baker underwent a quadruple bypass at WellSpan York Hospital. As a result of the use of the Sorin 3T Heater-Cooler System during his surgery, Mr. Baker was exposed to NTM.

10. Plaintiff and proposed Class Representative Jack Miller is an adult individual, a resident and citizen of Pennsylvania residing in York, PA. On March 27, 2015, Mr. Miller underwent a triple bypass at WellSpan York Hospital. As a result of the use of the Sorin 3T Heater-Cooler System during his surgery, Mr. Miller was exposed to NTM.

11. Defendant LivaNova PLC ("LivaNova") is a foreign for-profit corporation incorporated under the laws of England and Wales with a headquarters in Milan, Italy. LivaNova is a global medical device company specializing in, among other products, devices used in the treatment of cardiovascular diseases. LivaNova pursuant to a merger agreement

between Sorin Group S.p.A[1] and non-party, Cybertronics, Inc., advised purchasers in the United States it is the responsible party for Sorin 3T Heater-Cooler Systems. Further it was the recipient of various communications from the FDA regarding safety concerns about the 3T System. *See* the letters attached as Exhibits A through D.

12. Defendant, Sorin Group Deutschland Gmbh ("Sorin") is a foreign for profit corporation headquartered in Munich, Germany. Sorin designed, manufactured and marketed the Sorin 3T Heater-Cooler System used in Plaintiffs' and Class Members' surgeries. In October 2015, Sorin merged with and into LivaNova, with LivaNova continuing as the surviving company.

13. Defendant, Sorin Group USA, Inc. ("Sorin USA") is a U.S. designer, manufacturer, marketer and distributor of the Sorin 3T Heater-Cooler System, with a principal place of business in Arvada, Colorado. As set forth in LivaNova's Form 10-Q filed with the Security and Exchange Commission, Defendants, Sorin and Sorin USA, are wholly owned subsidiaries of LivaNova. Each Defendant markets and sells products under the LivaNova name.

GENERAL FACTUAL ALLEGATIONS

A. Two Central Pennsylvania Hospitals Announce Patient Exposure to Deadly Bacteria

14. On or about October 26, 2015, WellSpan announced that 1300 of its patients were exposed to a rare and potentially fatal bacteria during open heart surgeries.

[1] Upon information and belief, Sorin Group S.p.A. was the original holding company of Defendants, Sorin Group Deutschland Gmbh and Sorin Group USA, Inc.

15. According to WellSpan, those at risk include patients who underwent open heart surgery at its facility during a roughly four year period between October 1, 2011 and July 24, 2015.

16. On or about November 10, 2015, Hershey Medical Center announced that 2300 of its patients were exposed to the same rare and potentially fatal bacteria during open heart surgeries.

17. Hershey Medical Center stated that those at risk include patients who underwent open heart surgery at its facility between November 5, 2011 and November 5, 2015.

18. In addition to announcements to the public, both hospitals reported that they sent letters to individual patients which informed them of the exposure and advised them to follow up with their physicians.[2]

B. The Fatal Bacteria

19. The bacteria at issue, known as nontuberculous mycobacterium ("NTM")[3] occurs naturally in the environment and rarely causes illness. However, NTM poses a unique health risk to those with compromised immune systems, and in particular those who have undergone invasive surgical procedures.

20. Because NTM is a slow growing bacterium, it generally takes anywhere from two weeks to four years before manifestation of an NTM infection, which most commonly results in

[2] A true and correct copy of one such letter received by Plaintiff Edward Baker is attached hereto, made a part hereof, and marked Exhibit E.

[3] One particular strand of NTM called *M. chimaera* has been identified thus far. Discovery in this action may reveal that different strands of NTM, or other bacteria types altogether, have been transmitted to Plaintiffs and putative Class Members through the same mechanism. As such, Plaintiffs reserve their right to amend their Complaint with specific facts learned through discovery.

pulmonary or cardiovascular disease. The recommended monitoring period after exposure is at least four (4) years.

21. Symptoms of an NTM infection are very general and may include any combination of the following: fever, pain, redness, heat or pus around a surgical incision, night sweats, joint pain, muscle pain and fatigue.

22. Because NTM symptoms are non-specific and manifestation may take several weeks to several years, a patient will most likely fail to link the infection to his or her prior heart surgery, particularly as more time elapses between surgery and initial symptomatology.

23. The diagnosis of an NTM infection requires targeted culturing, molecular diagnostic testing and/or other screening processes not performed unless physicians are acutely aware of NTM exposure.

24. Most NTM infections are naturally resistant to common antibiotics. In order to overcome drug resistance, it is often necessary to take several different antibiotics at the same time. Depending on the severity of the infection, treatment may be needed for as long as two years.

25. While an NTM infection diagnosed early on may be successfully treated with a series of antibiotics, there is a significant risk of death in cases diagnosed late and in individuals with considerably weakened immune systems.

26. Upon information and belief, eight (8) individuals who underwent open heart surgery at WellSpan during the relevant time period have been diagnosed with an NTM infection. Of that infected group, five (5) subsequently died.

27. A joint investigation by the Centers for Disease Control ("CDC") and the Pennsylvania Department of Health ("PADOH") concluded that NTM was "likely a contributing factor" of these deaths.

28. Upon information and belief, three (3) individuals who underwent open heart surgery at Hershey Medical Center have been diagnosed with NTM infections.

C. Medical Devices Identified as the Infection Source

29. The CDC has affirmatively linked the NTM infection risk at WellSpan and Hershey Medical Center to the Sorin 3T Heater-Cooler System used to regulate patient blood temperature during cardiovascular surgeries.

30. The PADOH found that data "convincingly support[s] the conclusion that exposure to contaminated HCUs [heater-cooler units] is associated with NTM among patients undergoing open heart surgery on CPB [cardiopulmonary bypass]."[4]

31. Heater-cooler devices work by aerosolizing temperature controlled water. When the water used in the reservoir of the device contains even trace levels of NTM, the bacteria colonizes, and patients are exposed to the bacteria that are aerosolized through the device's exhaust vent.

32. The airborne transmission of NTM from contaminated heater-cooler units was recognized as a patient risk throughout Europe as early as 2011.

[4] Pennsylvania Department of Health Advisory # 322, dated December 11, 2015, available online at http://www.health.pa.gov/Your-Department-of-Health/Offices%20and%20Bureaus/epidemiology/Documents/PA%20HAN/2015/2015-PAHAN-322-12-10-NTM%20guidance_final_S.pdf (last accessed on January 21, 2016).

33. A Rapid Risk Assessment released by the European Centre for Disease Prevention and Control ("ECDC") in April 2015 notes that invasive cardiovascular infections identified as NTM have been reported in Switzerland, Germany and the Netherlands since 2011.[5]

34. A public health investigation in Switzerland included microbiological examinations of environmental samples that identified *M. Chimaera* (a strand of NTM) contamination in heater-cooler units, including water samples from the units. Air sampling cultures were positive for *M. chimaera* when the units were running, but negative when they were turned off. [6]

35. In July 2015, an article was published in the Journal of Clinical Infectious Diseases following patients in Europe who contracted NTM. The article concluded that the epidemiological and microbiological features of the prolonged outbreak in Europe provided evidence of the airborne transmission of *M. Chimaera* from contaminated heater-cooler units.

36. On October 15, 2015, the Food and Drug Administration ("FDA") issued a Safety Communication which noted that between January 2010 and August 2015, the agency received 32 Medical Device Reports of patient infections associated with heater-cooler device contamination, 8 in the U.S, and the remaining 24 predominantly from Western Europe.

37. On October 21, 2015, the Centers for Disease Control and Prevention ("CDC") issued an Interim Practical Guidance communication intended to raise awareness among health

[5] ECDC Rapid Risk Assessment, Invasive Cardiovascular Infection by Mycobacterium Chimaera Potentially Associated with Heater-Cooler Units Used During Cardiac Surgery, April 30, 2015, available online at http://ecdc.europa.eu/en/publications/Publications/mycobacterium-chimaera-infection-associated-with-heater-cooler-units-rapid-risk-assessment-30-April-2015.pdf (last accessed on January 26, 2016).
[6] *Id.*

departments, healthcare facilities and providers of the association between NTM infections and the use of heater-cooler devices.

D. Defendants' 3T Heater-Cooler System

38. The Sorin 3T Heater-Cooler Systems ("3T Systems") used at WellSpan and Hershey Medical Center during the relevant time periods were designed, manufactured, marketed and/or sold by Defendants LivaNova, Sorin and Sorin USA, to the hospitals in Pennsylvania.

39. On July 15, 2015, the FDA issued a Class 2 Recall of the 3T System because of "[p]otential colonization of organisms, including Mycobacteria, in Sorin Heater Cooler Devices, if proper disinfection and maintenance is not performed per instructions for use."

40. The recall directed customers to follow the new cleaning and disinfection procedures outlined in a Field Safety Notice issued by LivaNova and/or Sorin on June 15, 2015.

41. According this Field Safety Notice, the company's hygiene concept was "enhanced" by introducing the following modifications:

a) The use of filtered tap water when filling the device;

b) Instead of three different procedures (every five days, every 2 weeks and every 3 months), only two different procedures (every 7 days and every 14 days) to make disinfection easier;

c) The option to use peracetic acid instead of chloride solution;

d) H2O2 in low dose for preservation;

e) All external tubing, bottles and buckets were to be included in the disinfection process;

f) The use of polyethylene tubing that meets national drinking water standards; and

g) That unused heater-coolers must be disinfected bi-weekly.

42. However, a month prior to the recall, in May 2015, LivaNova and/or Sorin determined that devices that had not been maintained according to the manufacturer's instructions for use ("IFUs") for a long period of time required a mechanical deep disinfection process to remove bacterial colonization, referred to as "biofilm".

43. Upon information and belief, LivaNova and/or Sorin knew or should have known that design and/or manufacturing defects in its 3T System renders it prone to bacterial colonization, *regardless of the cleaning and disinfection procedures used*.

44. On December 11, 2015, the PADOH issued a Health Advisory[7] regarding heater-cooler systems and NTM infections, expressly acknowledging that the Sorin 3T System has the potential for the colonization and aerosolization of bacteria.

45. The Advisory questioned inconsistencies in the evolution of disinfection instructions from several heater-cooler manufacturers, including LivaNova and/or Sorin: "PADOH and PSA [Patient Safety Authority] observed significant differences in IFU from one version to the next published by the same manufacturer and between manufacturers. IFU also varied depending on prior maintenance and disinfection history. In addition, language from the

[7] Pennsylvania Department of Health Advisory # 322, dated December 11, 2015, available online at http://www.health.pa.gov/Your-Department-of-Health/Offices%20and%20Bureaus/epidemiology/Documents/PA%20HAN/2015/2015-PAHAN-322-12-10-NTM%20guidance_final_S.pdf (last accessed on January 21, 2015).

manufacturers was frequently ambiguous ("should" vs. "must") and some IFU were permissive of, but did not recommend, certain things (use of materials, chemical additives, procedures)."

46. The Advisory concluded that"[i]t is unknown whether risk of NTM infection can be completely eliminated given the paucity of data with which to validate device engineering and the manufacturers' most recent IFU."[8]

47. The Advisory also stated that the agencies "observed engineering differences that might predispose certain units to increased risk of biofilm and aerosolization of bacteria (e.g. blind segments of internal tubing, overflow tubes with low flow.)"[9]

48. The FDA recently raised significant questions about the safety and efficacy of the Sorin 3T System.

49. On December 29, 2015, the FDA sent LivaNova/Sorin a warning letter advising the company that its 3T Systems were subject to refusal of admission into the U.S. until it resolved several FDA violations, including the FDA's determination that the 3T Heater-Cooler Systems were adulterated[10] and misbranded and lacked requisite safety validation for several design changes to both the device itself as well as a series of revised disinfection instructions. The FDA's findings were based on its inspections of the company's Munchen, Germany and Arvada, Colorado production facilities.

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[8] *Id.*

[9] *Id. See also*, ECDC Rapid Risk Assessment, *supra* ("In Switzerland, cleaning and decontamination of the heater-cooler units was followed by recontamination. A new heater-cooler unit that initially tested negative for *M. Chimaera* at the hospital tested positive three months after purchase and installation.")

[10] Under the Federal Food, Drug and Cosmetic Act, a medical device is "adulterated" if the methods used in, or the facilities or controls used for their manufacture, packing, storage or installation are not in conformity with current good manufacturing practice requirements of the Quality System regulation.

50. In the letter, the FDA identified various design change orders dating back to December 11, 2012 which had never been submitted to the FDA for approval.

51. The letter also identified several changes to the disinfection instructions, dating back to December 20, 2011, which had never been reported to the FDA and which, like the current disinfection instructions, lacked proper efficacy validation.

E. Central Pennsylvania Hospitals Respond to the Crisis

52. Shortly after learning of the association between NTM infection and its 3T Heater- Cooler Systems, WellSpan created an on-site clinic for patients exposed to the bacteria to obtain screening for and medical treatment associated with diagnosed infections.

53. According to a website created by WellSpan for exposed patients[11], these medical services are currently being provided to patients at no cost.

54. According to a similar website maintained by Hershey Medical Center[12], Hershey is also providing free treatment for patients with confirmed NTM infections.

55. It is unknown how long WellSpan and Hershey Medical Center intend to continue offering these services. It is likewise unknown if there are any limitations to the services being offered by WellSpan and Hershey which may inhibit the early detection of NTM infections.

F. Patient Risk Due to Continued Use of the 3T System

56. In late July 2015, WellSpan reportedly replaced its 3T Heater Cooler systems with new equipment after consultation with the CDC and the PADOH. As of November 16,

[11] http://www.wellspan.org/yorkopenheart/patientinformation/ (last accessed on January 26, 2016)
[12] http://www.pennstatehershey.org/web/guest/patientcare/open-heart (last accessed on January 26, 2016)

2015, Hershey Medical Center also reported that it had replaced all of its heater-cooler devices with new equipment.

57. It is unknown to Plaintiffs whether WellSpan and Hershey Medical Center replaced their original 3T Systems with new 3T Systems of the same design, which are also prone to bacterial colonization and aerosolization.

58. Upon information and belief, other hospitals throughout this Commonwealth continue to use the Sorin 3T Heater-Cooler System, placing open heart surgery patients at significant risk of injury or death.

CLASS ACTION ALLEGATIONS

59. The Class claims all derive directly from a single course of conduct by the Defendants. The Defendants engaged in uniform and standardized conduct toward the Class. They did not differentiate, in degree of care or candor, their actions or inactions among individual Class members. The objective facts are the same for all Class members. Within each Claim for Relief, the same legal standards under Pennsylvania and/or federal law govern. Accordingly, Plaintiffs bring this lawsuit as a class action on their own behalf and on behalf of all other persons similarly situated as members of the proposed Classes pursuant to Federal Rule of Civil Procedure 23. This action satisfies the numerosity, commonality, typicality, adequacy, predominance, and superiority requirements of those provisions.

Class Definition

60. Plaintiffs seek to certify a class defined as follows:

All individuals residing in the Commonwealth of Pennsylvania

who underwent open heart surgery at:

1) WellSpan York Hospital between October 1, 2011 and July 24, 2015; or
2) Penn State S. Milton Hershey Medical Center between November 5, 2011 and November 5, 2015;

and who are currently asymptomatic for nontuberculous mycobacterium (or "NTM") infection. Claims for actual injury from an NTM infection are excluded from the claims brought in this class action.

61. Plaintiffs seek to certify the above defined Class for all causes of action alleged herein.

62. The prerequisites to maintaining a class action under Fed. R.Civ. P. 23(a) and (b) are met for the following reasons:

A. **Numerosity:** Upon information and belief, Plaintiffs state that there are at least 3600 individuals who underwent open heart surgery during the relevant time periods. Therefore, the proposed Class is so numerous that joinder of all individual members is impractical.

B. **Commonality:** Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual Class members. Among the questions of law and fact common to Plaintiffs and Class Members are:

1. Whether and the degree to which they were exposed to NTM during their surgeries;

2. Whether they were exposed to NTM at rates higher than, or through a more dangerous manner than, the general population;

3. Whether the 3T System is the source of their NTM exposure;

4. Whether the Defendants knew or should have known of their NTM exposure;

5. Whether their exposure to NTM was caused by the negligence of the Defendants;

6. Whether the 3T System is defectively designed;

7. Whether safer alternative designs for the 3T System existed which could have prevented the colonization and aerosolization of bacteria;

8. Whether the 3T System used in their surgeries contained manufacturing defects;

9. Whether the 3T System is unsafe for its intended use; and

10. Whether the Defendants are legally responsible for implementing and maintaining a medical monitoring fund to provide NTM screening.

C. **Typicality:** Plaintiffs' claims are typical of the claims of Class Members because they each underwent heart surgeries at WellSpan or Hershey Medical Center during the time period in which the allegedly defective medical devices were used. Plaintiffs allege that their exposure to NTM occurred in substantially the same way. As such, the claims or defenses of the representative parties are typical of the claims or defenses of the class.

D. **Adequacy of Representation:** Plaintiffs will fairly and adequately protect the interests of Class Members. Plaintiffs have retained counsel competent and

experienced in complex class action litigation and with adequate resources to assure the interests of the Class will not be harmed. The named Plaintiffs are typically situated and have no conflict of interest with the Class as a whole.

E. **Class Action Maintainable under Rule 23(b)(2):** A class action is appropriate because common questions of law and fact predominate over any individual questions affecting only individual members. Class treatment is superior to the alternatives for the fair and efficient adjudication of the controversy alleged herein. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single form simultaneously, efficiently, and without the duplication of effort and expense that numerous individual actions would entail. No difficulties are likely to be encountered in the management of this class action that would preclude its maintenance as a class action, and no superior alternative exists for the fair and efficient adjudication of this controversy. Without a class action, the Defendants will remain free from responsibility for exposing at least 3600 patients to a potentially deadly bacterium and Class Members, who have limited resources, will either be forced to fund their own medical screening or forgo the necessary screening due to financial constraints.

F. **Class Action Maintainable Under Rule 23(b)(3):** By negligently exposing Plaintiffs and Class Members to NTM, the Defendants have acted or refused to act on grounds generally applicable to the Class, thereby making the

implementation and maintenance of a medical monitoring fund and declaratory relief the appropriate remedies for the Class.

G. **Ascertainability:** The Class Members are ascertainable as both WellSpan and Hershey Medical Center can identify every single class member from their respective contemporaneously kept medical records. Accordingly, nothing more than a ministerial act on the part of non-parties WellSpan and Hershey Medical Center will be necessary to ascertain all potential Class Members.

TOLLING OF THE STATUTE OF LIMITATIONS

Discovery Rule

63. Under Pennsylvania law, the discovery rule tolls the statute of limitations when a plaintiff, due to facts or circumstances not within his or her control, is unable to discover his injury and its cause within the prescribed time period.

64. Under the discovery rule, the statute of limitations begins to run when a plaintiff knows, or in the exercise of reasonable diligence should have known: 1) that he or she has been injured, and 2) that his or her injury was caused by the conduct of another.

65. Prior to WellSpan York Hospital and Penn State Milton Hershey Medical Center's October and November 2015 announcements and correspondence advising that Plaintiffs and Class Members may have been exposed to NTM, Plaintiffs were wholly unaware of both their exposures to NTM and the fact that their exposures may have been caused by a defective medical device.

66. Any applicable statute of limitation has therefore been tolled by Plaintiffs' and Class Members' lack of knowledge of the facts alleged herein prior to October and November 2015.

COUNT I
MEDICAL MONITORING
Plaintiffs v. All Defendants

67. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein.

68. The latency period for the manifestation of an NTM infection is estimated to be between anywhere from two weeks to five years after exposure.

69. Plaintiffs and Class Members have been exposed to NTM at rates higher than, or in a substantially more dangerous manner than, the general population. Plaintiffs' exposure levels are therefore substantial in nature.

70. When NTM is transmitted in the method described above, namely airborne transmission from a contaminated medical device to an individual undergoing invasive heart surgery, it is widely acknowledged as a dangerous and potentially life-threatening bacteria.

71. Plaintiffs' and the Class Members' exposure to NTM was caused by Defendants' negligence as follows:

a) Failing to conduct adequate safety and efficacy testing before seeking to have the 3T System put into the stream of commerce;

b) Failing to notify the FDA of design change orders to the 3T System;

c) Supplying "validation" studies to the FDA which failed to demonstrate the safety and efficacy of cleaning and disinfection procedures for the 3T System;

d) Failing to warn Plaintiffs and Class Members of the potential for bacterial colonization and patient exposure to such bacteria;

e) Designing the 3T System in such a way that it is prone to bacterial colonization and aerosolization; and

f) Failing to ensure proper workmanship, materials and labeling for the 3T System.

72. Plaintiffs' and the Class Members' exposure to NTM was proximately caused by Defendants' negligence as described herein.

73. Monitoring procedures exist that make the detection of NTM infections possible.

74. NTM infections are capable of early detection by way of existing scientific methods including, but not limited to, targeted culturing and DNA sequencing of invasive samples (e.g., blood, pus, tissue biopsy or implanted prosthetic material).

75. Because NTM screening is not conducted in the absence of exposure to NTM, the prescribed monitoring regime is different from that normally recommended in the absence of exposure. Plaintiffs and Class Members require specialized screening not within the purview of routine medical exams.

76. The prescribed monitoring regime is reasonably necessary according to contemporary scientific principles in order to provide for early diagnosis of NTM infections leading to benefits in treatment, management, rehabilitation and prevention or mitigation of long term health consequences, including death.

COUNT II
DECLARATORY RELIEF PURUSANT TO 28 U.S.C. § 2201, *ET SEQ.*
Plaintiffs v. All Defendants

77. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein.

78. Pursuant to 28 U.S.C. § 2201, a court may "declare the rights and legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought."

79. Declaratory relief is intended to minimize "the danger of avoidable loss and unnecessary accrual of damages." 10B Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, *Federal Practice and Procedure* § 2751 (3d ed. 1998).

80. Plaintiffs allege that the Sorin 3T Heater-Cooler System is defective in that it is prone to bacterial colonization which may be transmitted to patients during surgery.

81. There are actual controversies between the Defendants and Plaintiffs, including prospective Class members, concerning: 1) whether the 3T System is defective, 2) whether the Defendants knew, or should have known, of defects in their 3T System, and 3) whether the Defendants failed to adequately warn of the risk of bacterial colonization in their 3T System.

82. The declaratory relief requested herein will generate common answers that will settle the controversy related to the alleged defects in the Sorin 3T System. There is an economy to resolving this issue as it has the potential to eliminate the need for continued and repeated litigation regarding alleged defects in this medical device.

83. Plaintiffs therefore seek a declaration that the Sorin 3T Heater-Cooler System is defective, and that the Defendants must expeditiously notify the Class of such defects.

PRAYER FOR RELIEF

Plaintiffs, on behalf of themselves and all others similarly situated, request the Court to enter judgment against the Defendants as follows:

A. An order certifying the proposed Class and designating Plaintiffs as the named representatives of the Class, and designating the undersigned as Class Counsel;

B. A declaration that the Sorin 3T Heater-Cooler System is defective and unsafe for its intended use;

C. A declaration that the Defendants are financially responsible for implementing and maintaining a fund for the medical monitoring of Plaintiffs and Class Members;

D. An award to Plaintiff and Class Members of damages, costs and disbursements in this action, including reasonable attorneys' fees, as permitted by law;

E. An award of pre-judgment and post-judgment interest, as provided bylaw;

F. Leave to amend this Complaint to conform to the evidence produced at trial; and

G. Such other relief as may be appropriate under the circumstances.

JURY TRIAL DEMANDED

Plaintiffs demand a trial by jury on all issues so triable.

Dated: March 21, 2016

Respectfully submitted,

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